

**REMARKS**

Claims 42, 45 and 55-70 are pending in the subject application. Applicants have herein amended claim 42. Support for amended claim 42 can be found in the specification at, *inter alia*, page 40, lines 14 and 15 and page 26, lines 27-29. Applicants have also canceled claim 58 without prejudice or disclaimer. Applicants maintain that this Amendment raises no issue of new matter. Accordingly, upon entry of this Amendment, claims 42, 45, 55-57 and 59-70 will be pending and under examination in the subject application.

**August 15, 2006 Examiner's Interview**

Applicants wish to thank the Examiner for his time and consideration during the August 15, 2006 telephonic interview with Alan J. Morrison, applicants' undersigned attorney. During the interview, the Examiner and Mr. Morrison discussed amendments to the claims which, if made, might further the prosecution of this application. Applicants direct the Examiner to the amendments and remarks made herein, which applicants maintain address the issues discussed during the interview.

**Double Patenting Rejection**

The Examiner provisionally rejected claims 42, 45 and 55-70 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-3

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and 16 of copending U.S. Serial No. 08/905,709 and claims 36, 39, 40 and 53 of copending U.S. Serial No. 09/498,459.

In response, applicants will respond to this rejection once it is no longer provisional.

**Rejections under 35 U.S.C. §102(b)**

The Examiner rejected claims 42, 45, 55, 57-61, 63-68 and 70 under 35 U.S.C. §102(b) as allegedly anticipated by WO 97/26913 ("the '913 application").

In response to the rejection of claim 58, applicants note that claim 58 has been canceled herein. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of the remaining claims, applicants respectfully traverse.

Claim 42, as amended provides a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject. This method comprises administering to the subject a binding-inhibiting amount of a compound other than sRAGE, which compound (i) comprises a fragment of sRAGE, and (ii) is capable of inhibiting binding of the  $\beta$ -sheet fibril to RAGE, wherein the  $\beta$ -sheet fibril is formed from an amyloid- $\beta$  peptide selected from the group consisting of A $\beta$  (1-39), A $\beta$  (1-40), A $\beta$  (1-42) and A $\beta$  (1-40) Dutch variant, so as to thereby prevent and/or treat a disease involving  $\beta$ -sheet

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fibril formation other than Alzheimer's Disease in the subject.

In order for the claims to be anticipated by the '913 application, this reference would have to teach each and every element thereof. The '913 application fails to do so.

Specifically, the Examiner alleges that despite the failure of the '913 application to recite a "compound comprising a fragment of sRAGE", claim 42 is nonetheless anticipated based upon its recitation of the term "comprising" which allows for more than what is included in a "fragment of sRAGE." Accordingly, the Examiner alleges that the '913 application, which teaches, in part, a method which comprises administering sRAGE to a subject, anticipates a method which comprises administering a compound comprising a fragment of sRAGE.

Applicants direct the Examiner's attention to amended claim 42, which provides, in relevant part, a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound *other than sRAGE*, which compound (i) comprises a fragment of sRAGE and (ii) is capable of inhibiting binding of the  $\beta$ -sheet fibril to RAGE. Accordingly, applicants maintain that the '913 application fails to teach each and every element of claim 42.

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The Examiner also rejected claims 42-45, 55, 57-68 and 70 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 5,864,018 ("the '018 patent).

In response to the rejection of claim 58, applicants note that claim 58 has been canceled herein. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of the remaining claims, applicants respectfully traverse.

The '018 patent fails to teach a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound comprising a fragment of sRAGE, but not sRAGE, *wherein the  $\beta$ -sheet fibril is formed from an amyloid- $\beta$  peptide selected from the group consisting of A $\beta$  (1-39), A $\beta$  (1-40), A $\beta$  (1-42) and A $\beta$  (1-40) Dutch variant.*

On page 6 of the July 17, 2006 Final Office Action, the Examiner concedes that although the '018 patent teaches amyloid- $\beta$  peptide, the '018 patent does not teach the amyloid beta peptides A $\beta$  (1-39), A $\beta$  (1-40), A $\beta$  (1-42) and A $\beta$  (1-40) Dutch variant. Accordingly, the '018 patent fails to teach each and every element of claim 42. Claims 45, 55, 57, 59-68 and 70, which depend upon claim 42, are also not anticipated by the '018 patent.

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Accordingly, applicants maintain that claims 42, 45, 55, 57, 59-68 and 70 satisfy the requirements of 35 U.S.C. §102(b).

**Rejection under 35 U.S.C. §103(a)**

The Examiner also rejected claims 42, 45 and 55-70 under 35 U.S.C. §103(a) as allegedly obvious over the '018 patent, in view of Lilley, et al. and further in view of Kelley.

In response to the rejection of claim 58, applicants note that claim 58 has been canceled herein. Accordingly, the Examiner's rejection thereof is moot.

In response to the rejection of the remaining claims, applicants respectfully traverse.

In order to find the subject invention obvious over the '018 patent in view of Lilley, et al. and Kelley, the prior art references, in combination, must, among other things, teach or suggest all the elements thereof. The '018 patent, Lilley, et al. and Kelley fail to do this.

As discussed above, nowhere does the '018 patent teach or suggest a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's Disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound comprising a fragment of sRAGE, but not sRAGE, wherein the  $\beta$ -sheet fibril is formed from an amyloid- $\beta$  peptide selected

*from the group consisting of A $\beta$  (1-39), A $\beta$  (1-40), A $\beta$  (1-42) and A $\beta$  (1-40) Dutch variant. Specifically, as discussed above, the '018 patent does not teach the amyloid- $\beta$  peptides A $\beta$  (1-39), A $\beta$  (1-40), A $\beta$  (1-42) and A $\beta$  (1-40) Dutch variant.*

Lilley, et al., teach that diabetes mellitus is associated with delayed wound healing, and Kelley teaches that prion diseases result from  $\beta$ -sheet fibril formation. These references fail to cure the deficiency of the '018 patent, in that they also fail to teach or suggest the element of inhibiting  $\beta$ -sheet fibril to RAGE, wherein the  $\beta$ -sheet fibril is formed from an amyloid- $\beta$  peptide selected from the group consisting of A $\beta$  (1-39), A $\beta$  (1-40), A $\beta$  (1-42) and A $\beta$  (1-40) Dutch variant.

Accordingly, applicants maintain that the cited references combined do not teach or suggest all the elements of the claimed invention.

Applicants maintain that claims 42, 45 and 55-57 and 59-70 satisfy the requirements of 35 U.S.C. §103(a).

### **Summary**

In view of the above remarks, applicants maintain that the pending claims are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in

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advancing the prosecution of the subject application,  
applicants' undersigned attorneys invite the Examiner to  
telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of  
this Amendment. However, if any fee is required,  
authorization is hereby given to charge the amount of such  
fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White  
Registration No. 28,678  
Alan J. Morrison  
Registration No. 37,399  
Attorneys for Applicants  
Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, New York 10036  
Tel. No. (212) 278-0400

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 8/18/02  
Alan J. Morrison Date  
Reg. No. 37,399